

IN THE
UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	: 10/501,112	Confirmation No.	: 5620
Applicant	: Benkowski et al.	Assignee	: MICROMED TECHNOLOGY, INC.
Filed	: 07/07/2004		
TC/A.U.	: 3762	Title	: Blood Pump System and Method of Operation
Examiner	: George R. Evanisko		
Docket No.	: 0021906.023US		
Customer No.	: 22904		

Mail Stop Appeal
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REPLY BRIEF

I. Real party in interest

Please refer to the Appeal Brief filed January 6, 2010.

II. Related appeals and interferences

Please refer to the Appeal Brief filed January 6, 2010.

III. Status of claims

Please refer to the Appeal Brief filed January 6, 2010. Additionally, Appellant understands that the Examiner has withdrawn the rejections of claims 3, 6, 10, and 27. Thus, claims 1-15, 19, 20, and 24-28 are currently pending, with claims 1, 2, 4, 5, 7-9, 11-15, 19, 20, 24-26, and 28 being rejected. The rejections of claims 1, 2, 4, 5, 7-9, 11-15, 19, 20, 24-26, and

28 are presently being appealed. Appellant understands that claims 3, 6, 10, and 27 would be allowable if rewritten in independent form. Claims 16-18 and 21-23 have been canceled.

IV. Status of amendments

Please refer to the Appeal Brief filed January 6, 2010.

V. Summary of claimed subject matter

Please refer to the Appeal Brief filed January 6, 2010.

VI. Grounds of rejection to be reviewed on appeal

Claims 1, 2, 4, 5, 7-9, 11-15, 19, 24-26, and 28 stand rejected under 35 U.S.C. 102(e) as being anticipated by Medvedev et al., U.S. Patent Application Publication No. 20040152944. Dependent claim 20 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Medvedev. Appellant appeals each rejection of claims 1, 2, 4, 5, 7-9, 11-15, 19, 20, 24-26, and 28.

VII. Argument

Please refer to the Appeal Brief filed January 6, 2010. Additionally, Appellant offers the following responses to the Examiner's Answer.

i. Claims 1 and 26

Claims 1 and 26 each recite (emphasis added) “***extracting*** the patient’s ***diastolic pump flow rate*** from the pump flow rate, wherein the diastolic pump flow rate is a ***separately isolated***

flow contribution below a **mean pump flow rate**".

As previously argued, while Medvedev discusses average minimum peaks being "associated with ventricular diastole", nowhere does he actually teach "**extracting** the patient's diastolic pump flow rate as the flow contribution below a mean pump flow rate", emphasis added, as claimed in claims 1 and 26. Rather, as previously argued, Medvedev is only concerned with the average of the minimum peaks (over multiple cardiac cycles), which he **associates** with ventricular diastole, rather than an actual **extracted or separately isolated diastolic flow rate**.

The Examiner appears to err in failing to recognize that Medvedev's average of peaks cannot actually represent any true diastolic pump flow rate. This average of peaks is an average of extremes. Therefore, Medvedev's average of peaks is necessarily skewed low and cannot actually represent any true diastolic pump flow rate. For example, as previously argued, in highly irregular flow waveforms and in those exhibiting large negative excursions, such as ventricular suction, the average of those peaks will be significantly lower than an actual measured diastolic flow rate. This divergence can cause a system such as Medvedev's, to overreact.

In any case, Medvedev's average of peaks is simply not the same thing as "**extracting** the patient's diastolic pump flow rate from the pump flow rate, wherein the diastolic pump flow rate is a **separately isolated flow contribution** below a mean pump flow rate", emphasis added, as claimed in claims 1 and 26. At the very least, this limitation is not described in Medvedev as set forth in the claims.

ii. **Claim 7**

Claim 7 recites "**a controller having an input for receiving a blood pump flow rate**

signal, the controller being programmed to extract a separate diastolic pump flow rate from the blood pump flow rate signal”, emphasis added.

Appellant acknowledges that Medvedev's controller does have inputs and those inputs do receive signals. However, those inputs are used to receive speed and current signals, not any flow rate signal. That is because Medvedev **calculates** flow from those speed and current signals. Under ideal conditions, flow rate can be calculated from current and speed. But, as discussed at length in the Appeal Brief filed January 6, 2010, there are numerous situations where such a calculation would yield erroneous results. In any case, Medvedev calculates flow **internally**, in his controller, and therefore his controller simply does not have, nor need, “**an input for receiving a blood pump flow rate signal**,” as claimed

The Examiner appears to err in interpreting the claim term “a blood pump flow rate signal”. Appellant urges the Board to recognize that meaning must be given to “blood pump flow rate signal” beyond just “signal”, as offered by the Examiner. The descriptor “blood pump flow rate” must mean something; it must somehow modify “signal”. The claim does not merely recite something like “a signal” or “a signal from which flow rate may be determined”. Rather, the claim term limits the signal to “a blood pump flow rate signal”.

Appellant urges the Board to recognize that “blood pump flow rate signal” means just that, as anyone skilled in the art would readily recognize, namely, a signal indicative of, or representing, flow rate through a blood pump. Furthermore, as the “blood pump flow rate signal” is received at an input of the claimed controller, the “blood pump flow rate signal” must necessarily be produced beyond the input of the claimed controller, in order to meet any reasonable interpretation of the claim.

In any case, Medvedev's controller receiving speed and current signals is simply not the same thing as “**a controller having an input for receiving a blood pump flow rate signal**,”

the controller being programmed to extract a separate diastolic pump flow rate from the blood pump flow rate signal”, emphasis added, as claimed in claim 7. At the very least, this limitation is not described in Medvedev as set forth in the claim.

iii. Claim 8

Claim 8 recites “further comprising an ***implantable flow measurement device*** having an ***output for providing the flow rate signal***”, emphasis added. Claim 8 depends from claim 7, which also recites “a pump” and “a controller having an ***input for receiving a blood pump flow rate signal***, the controller being programmed to extract a separate diastolic pump flow rate from the blood pump flow rate signal”, emphasis added. Thus, claim 8 explicitly requires a flow measurement device that provides a “***flow rate signal***”, which anyone reading the claim and/or the specification would understand to be indicative of a flow rate. Furthermore, claim 8 requires the “implantable flow measurement device” to provide “the flow rate signal” to “an input” of the controller.

In contrast, as previously argued, Medvedev teaches no flow rate signal. Medvedev teaches no device “having an output for providing the flow rate signal”, much less any controller having an ***input*** for receiving the flow rate signal provided by any device having any such output. Rather, Medvedev calculates flow and/or pressure from the current, voltage, and/or speed of his pump, ***internally*** to his controller. This, of course, leads to the potential problems explained in the Appeal Brief filed January 6, 2010, such as general inaccuracy problems and an inability to detect or account for obstructions and/or mechanical problems.

The Examiner appears to err in interpreting the claim term “an ***implantable flow measurement device*** having an ***output for providing the flow rate signal***”. More specifically, the Examiner appears to err in interpreting the claim terms “an ***input for receiving a blood***

pump flow rate signal', "an **output for providing the flow rate signal**", and "**flow rate signal**". Apparently, as best understood, the Examiner appears to suggest that Medvedev's internal calculation of flow based on received current, speed, and/or voltage signals, meets the limitations of the claim.

However, the Examiner fails to show how Medvedev teaches "device having an output for providing **the** flow rate signal", received by the controller, much less "a controller having an input for receiving a blood pump flow rate signal", as set forth in the claim. Appellant urges the Board to recognize that meaning must be given to the claimed "input" and "output", just as meaning must be given to "flow rate signal" beyond just "signal", as offered by the Examiner. As discussed above, the descriptor "flow rate" must mean something; it must somehow modify "signal". Appellant urges the Board to recognize that "flow rate signal" means just that, as anyone skilled in the art would readily recognize, namely, a signal indicative of, or representing, flow rate. This, of course, requires that the "implantable flow measurement device" actually provide the flow rate signal, indicative of an actual flow rate, **to** the controller.

Similarly, the terms input and output, as used in the specification and claims, necessarily require that a signal is transmitted and received between devices. This is the meaning anyone skilled in the art would understand. This is the meaning Medvedev uses when he talks about the current, speed, and voltage inputs to his microcontroller 18, in paragraphs [0047] and [0048]. This is also the meaning Medvedev uses when he talks about the "speed output" of his motor drive, in paragraph [0065]. Thus, the claim terms input and output necessarily require that a signal is transmitted and received between devices, i.e. a signal is provided **from** one device **to** another.

To suggest that one device, such as Medvedev's controller, would have both "an output for providing **the** flow rate signal" and "an input [connected to that output] for receiving a blood

pump flow rate signal” stretches imagination beyond reason. Yet, this appears to be the fiction offered by the Examiner. Medvedev does not appear to teach this. As discussed, Medvedev’s microcontroller 18 calculates his flow rate. Appellant can find no discussion of Medvedev’s microcontroller 18 outputting any flow rate signal to any controller “programmed to extract a separate diastolic pump flow rate from the blood pump flow rate signal”.

In any case, Medvedev’s internal calculation of flow is simply not the same thing as “an implantable flow measurement device having an output for providing the flow rate signal”, as claimed. Thus, it cannot be said that “each and every element as set forth in the claim is found, either expressly or inherently described, in” Medvedev, as is required by the applicable case law. As a result, Medvedev simply does not anticipate “further comprising an implantable flow measurement device having an output for providing the flow rate signal”, as claimed in claim 8.

iv. Claim 19

Claim 19 recites “further comprising an implantable pressure sensor for providing pressure sensor data to the controller.” The Examiner acknowledges that Medvedev does not include “an extra hardware pressure sensor”.

The Examiner appears to err in asserting that Medvedev’s controller calculating pressure anticipates this limitation. Appellant again urges the Board to give meaning to the words in the claim. Appellant urges the Board to recognize that “further comprising an implantable pressure sensor for providing pressure sensor data to the controller”, as claimed explicitly requires an extra “sensor for providing **pressure** sensor data **to the controller**”. At the very least, the claim requires data, indicative of pressure, to be provided to the controller. The claim does not merely recite something like “data” or “data from which pressure may be determined”. Rather, the claim term limits the data to “pressure sensor data”, and therefore requires an actual pressure

sensor for “providing pressure sensor data to the controller.”

In contrast, Medvedev calculates pressure internally to his controller, and therefore does not **further comprise**, and explicitly teaches away from **further comprising**, any “extra” sensor for providing such data to the controller.

In any case, Medvedev’s internal calculation of pressure is simply not the same thing as “further comprising an implantable pressure sensor for providing pressure sensor data to the controller”. Thus, it cannot be said that “each and every element as set forth in the claim is found, either expressly or inherently described, in” Medvedev, as is required by the applicable case law. As a result, Medvedev simply does not anticipate “further comprising an implantable pressure sensor for providing pressure sensor data to the controller”, as claimed in claim 19.

v. Claim 20

As an initial matter, Appellant points out that Appellant has challenged the Examiner’s rejection and reasoning in support thereof. Appellant has not been made aware of anything that would support taking Official Notice that prior art systems use an actual sensed pressure to determine diastolic flow rate, as claimed. Rather, the only support for such a proposition is Appellant’s own disclosure. Of course, as discussed below, Medvedev does not include an actual pressure sensor. Therefore, is it difficult to understand the offered Official Notice.

Claim 20 recites “wherein the pressure sensor data from the pressure sensor is used to derive separate diastolic pump flow rate information.” Claim 20 depends from claim 19, which depends from claim 7. Claim 19 recites “further comprising an implantable pressure sensor for providing pressure sensor data to the controller.” Thus, claim 20 requires “an implantable pressure sensor for providing pressure sensor data to the controller”, with that sensor data being “used to derive separate diastolic pump flow rate information.”

The Examiner appears to err in asserting that Medvedev's controller calculating pressure from flow renders this limitation obvious. However, as previously argued, Medvedev teaches a pressure being derived from flow, not the other way around, as claimed. See, for example, paragraph [0035]. Furthermore, Medvedev's "mean **systemic** pressure P", which is what Medvedev actually derives, would have little, if any, bearing on the claimed "**diastolic** pump flow rate", emphasis added.

In any case, Medvedev's calculation of a pressure from a calculated flow is simply not suggestive of "an implantable pressure sensor for providing pressure sensor data **to** the controller", emphasis added, with that sensor data being "used to derive separate diastolic pump flow rate information", as claimed.

In fact, as discussed above and in the Appeal Brief filed January 6, 2010, Medvedev actually teaches away from this combination of claim limitations. Thus, Medvedev simply cannot be said to support a legal conclusion of obviousness of "an implantable pressure sensor for providing pressure sensor data to the controller", much less with that pressure sensor data being "used to derive separate diastolic pump flow rate information", as claimed. As a result, the present obviousness rejection simply cannot be sustained.

For at least these reasons, Appellant respectfully submits that the presently pending claims are patentable over the disclosure and teaching of the prior art made of record. These rejections are therefore appealed and Assignee respectfully requests they be overruled.

Respectfully submitted,

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